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NOTICE OF ALLOWANCE AND FEE(S) DUE

12/10/2004

Brian R Morrill Esq Biomeasure Incorporated 27 Maple Street Milford, MA 01757-3650

EXAMINER FUBARA, BLESSING M ART UNIT PAPER NUMBER 1615

DATE MAILED: 12/10/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR -	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,692	07/15/2002	Thomas Ciaran Loughman	50165/013001	4672

TITLE OF INVENTION: PROCESS TO MAKE A SUSTAINED RELEASE FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$0	\$1400	03/10/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current **SMALL ENTITY status:**

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B -Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

- II. PART B FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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Brian R Morrill I Biomeasure Incorp 27 Maple Street Milford, MA 0175	porated			I hereby certify that the States Postal Service addressed to the Ma	rtificate of Mailing or Transhis Fee(s) Transmittal is bein with sufficient postage for fir il Stop ISSUE FEE address PTO (703) 746-4000, on the c	g deposited with the Unite st class mail in an envelor above, or being facsimi
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PLEASE NOTE: Unless recordation as set forth in	s an assignee is identified b n 37 CFR 3.11. Completion	elow, no assignee of this form is NO	data will appear T a substitute for	r on the patent. If an assign	nee is identified below, the d	locument has been filed for
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The Director of the USPTO NOTE: The Issue Fee and F interest as shown by the rec	is requested to apply the Iss Publication Fee (if required) cords of the United States Pat	ue Fee and Publica will not be accepted ent and Trademark	ation Fee (if any) d from anyone of Office.	or to re-apply any previous ther than the applicant; a reg	ly paid issue fee to the applica istered attorney or agent; or th	ation identified above. ne assignee or other party in
Authorized Signature				Date		

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Brian R Morrill E. Biomeasure Incorpo			FUBARA, BI	LESSING M
27 Maple Street	ласа		ART UNIT	PAPER NUMBER
Milford, MA 01757	-3650		1615	

DATE MAILED: 12/10/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 452 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 452 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

	Application No.	Applicant(s)
•	40/040 602	LOUGHMAN, THOMAS CIARAN
Notice of Allowability	10/049,692 Examiner	Art Unit
	Blessing M. Fubara	1615
The MAILING DATE of this communication appear II claims being allowable, PROSECUTION ON THE MERITS IS (erewith (or previously mailed), a Notice of Allowance (PTOL-85) of OTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHT of the Office or upon petition by the applicant. See 37 CFR 1.313	ars on the cover sheet with the OR REMAINS) CLOSED in this or other appropriate communical GHTS. This application is subjection	application. If not included tion will be mailed in due course. THIS
. X This communication is responsive to communication of 07/1	<u>15/02</u> .	
. ☑ The allowed claim(s) is/are <u>1-7</u> .		
. $igotimes$ The drawings filed on <u>15 July 2002</u> are accepted by the Exa	aminer.	
Acknowledgment is made of a claim for foreign priority und a)	been received. been received in Application No. uments have been received in the of this communication to file a regent of this application. Ited. Note the attached EXAMINIST reason(s) why the oath or declarst part of the properties of the submitted. Item on the comment of t	nis national stage application from the ply complying with the requirements ER'S AMENDMENT or NOTICE OF aration is deficient. TO-948) attached e Office action of awings in the front (not the back) of 21(d). L must be submitted. Note the
ttachment(s) . ☑ Notice of References Cited (PTO-892) . ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) . ☑ Information Disclosure Statements (PTO-1449 or PTO/SB/08 Paper No./Mail Date 5/17/02,6/20/02,9/2/04 . ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. Interview Summa Paper No./Mail 3), 7. Examiner's Ame	Date

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DETAILED ACTION

Examiner acknowledges receipt of request of change of correspondence address and associate power of attorney filed 07/19/04; preliminary amendment filed 07/15/02; IDS filed 09/21/04, 06/20/02 and 0/17/02.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In ser the abstract provided on a separate sheet of paper.

Allowable Subject Matter

1. The following is an examiner's statement of reasons for allowance:

Kim et al. (US 5,552,520, cited in applicants specification) discloses the synthesis of BIM-23190 Somatostatin agonist (column 19, lines 20-30), which is compound A of the instant claims. Kim differs from the instant claims in that Kim does not disclose reacting BIM-23190, the somatostatin agonist with a polymer that comprises lactide, glycolide and tartaric acid units where compound A (BIM 23190) ionically bonds to the polymer.

Shalaby et al. (US 5,672,659) discloses a composition that comprises polyester that is ionically conjugated to a bioactive polypeptide (abstract). The polyester is a member selected form the group consisting of L-lactic acid, D-lactic acid, DL-lactic acid, ε-caprolactone, p-dioxanone, e-caproic acid, substituted and unsubstituted trimethylene carbonate, 1,5-dioxepan-2-one, 1,4-dioxepan-2-one, glycolide, glycolic acid, L-lactide, D-lactide, DL-lactide, meso-lactide,

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alkylene oxalate, cycloalkylene oxalate, alkylene succinate, (β-hydroxybutyrate), and optically active isomers, racemates or copolymers of any of the above (column 1, line 55 to column 2, line 10). In Shalaby, the polyester is partially acid tipped with glutaric anhydride (column 2, lines 13-15). Somatostatin is one of the bioactive polypeptides that can ionically bond to the polyester and BIM-21003 is a somatostatin that is conjugated to d,l-lactide/glycolide/citric acid (column 2, line 29; column 12, lines 5-23) and in example 9, somatostatin tumor inhibiting analogue, BIM-23014 is conjugated to lactic/glycolide/malic copolymer. Shalaby differs from the instant claims in that Shalaby does not disclose a copolymer that contains tartaric acid; Shalaby does not also disclose the specific somatostatin derivative, BIM-23190; also, Shalaby does not disclose the ratio of glycolide to lactide that is recited by the instant claims; and Shalaby does not disclose the process of instant claim 1.

Culler et al. (US 6,268,342) discloses a composition that comprises somatostatin agonist, which has the structure of compound A of the instant claim (column 6, lines 35-45) and sustained release polymer such as lactic acid polymer or lactic-glycolic acid copolymer (column 10, lines 59-67). Culler differs from the instant claims in that Culler does not disclose that the polyester is ionically bonded to the somatostatin; Culler does not disclose that the polyester is tipped with tartaric acid and Culler does not teach the process of forming polyester-somatostatin ionic conjugate of the type recited in the instant claims.

Melmed et al. (US 5,972,893) discloses a method of treating hyperprolactinemia with a composition that contains somatostatin agonist (column 5, line 49) such as BIM-23190 (Examples 8 and 9) and when the composition is administered as a sustained release implant, the composition comprises lactic acid polymer or lactic acid co-glycolic acid copolymer (column 6, lines 51-60).

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Melmed differs from the instant claims in that Melmed does not disclose ionic conjugate of the somatostatin and the polyester; also the polymer of Melmed is not end tipped with tartaric acid.

The pending claims are thus allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara Patent Examiner Tech. Center 1600 James M. Spear JAMES M. SPEAR PRIMARY EXAMINER

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ABSTRACT OF THE DISCLOSURE

This invention pertains to a process for making a sustained release complex. Compound (I), which comprises Compound (A), having formula (A), and a copolymer comprising poly (I)-lactic-glycolic-tartaric acid (P (I) LGT), wherein the amino group of Compound (A) is ionically bound to a carboxyl group of the (P (I) LGT).

James M. Spead JAMES M. SPEAR PRIMARY EXAMINER A4 16 15

Notice of References Cited Application/Control No. 10/049,692 Examiner Blessing M. Fubara Document Number Date Date Document Number Date Name Applicant(s)/Patent Under Reexamination LOUGHMAN, THOMAS CIARAN Page 1 of 1 Classification

				U.S. PATENT DOCUMENTS	
*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	Α	US-5,552,520	09-1996	Kim et al.	530/311
	В	US-5,863,985	01-1999	Shalaby et al.	525/54.1
	С	US-6,268,342	07-2001	Culler et al.	514/12
	D	US-5,972,893	10-1999	Melmed et al.	514/16
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)

Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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SUBSTITUTE (MODIFIED)	FORM PTO-1449	PATENT ANI	TMENT OF COMMERCE D TRADEMARK OFFICE	Attorney Docket No. Serial No. Applicant		50165/013 10/049,69 Thomas C	
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(37 C.F.R. §1.9	38(b))			IDS Filed		May 13, 2	002
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Examiner's Initials	Document Number	Publication Date	Country or Patent Office		Class	Subclass	Translation (Yes/No)
BF	WO 01/12233 A2	22.02.01	bet MO		47	48	NO
BR	WO 97/39738	30.10.97	LET NO		9	16	NO
bf	WO 94/15587	21.7.94	pol WID		9	16	no
POC.	WO 95/04752	16.2.95	DET IN O		5	02	NO
	OTHER DOCL	JMENTS (INCLI	UDING AUTHOR, TITLE, [DATE, PLAC	E OF PUB	LICATION)	
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EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

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(MODIFIED)		PATENT AND) IRADEMARK OFFICE	Serial No.		10/049,69	2		
				Applicant		Thomas C	Thomas Ciaran Loughman		
		ON DISCLOSU IT BY APPLICA		Filing Date		February	15, 2002		
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(37 C.F.R. §1.9	98(b))			IDS Filed		June 14, 2	2002		
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Examiner's Initials	Document Number	Publication - Date	Country or Patent Office		Class	Subclass	Translation (Yes/No)		
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